getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. *Id.* at 9.

But the Act's framers did not limit their efforts to permitting licensing of generic drugs only after expiration of patents on name-brand drugs; rather, they made clear their intent that "a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired," so long as it alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. By placing the burden on the patent-holder to initiate litigation and by providing only for a limited stay of FDA approval of the generic even if such litigation was sought, the drafters provided that "the FDA will approve the generic application, even if the drug is still on patent." *Id.* Moreover, the legislation's backers rejected efforts to amend it to limit FDA authority to license generic versions of patented drugs because such amendments would "substantially delay generics from getting into the market when they seek to challenge the validity of a patent." *Id.* at 10.

The ultimate goal of all of these provisions was to "provide low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman). The legislators who voted for the Act anticipated that it "will do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because it will bring about lower priced generic alternatives to brand-name drugs once the patent has expired or if there is no valid patent and the courts decide there is no valid patent in order to give that monopoly protection." *Id.* (statement of Rep. Waxman).

II. Congress Reaffirmed Its Commitment to Competition Between Generic and Name-Brand Drugs When It Passed the Medicare Drug Benefit Legislation of 2003, Which Contained New Provisions to Combat Abuses That Had Arisen Under Hatch-Waxman.

Although the Hatch-Waxman Act achieved the purpose of streamlining the approval of generic versions of brand-name drugs, two decades of experience under the Act showed that pharmaceutical companies were sometimes able to use anti-competitive devices to thwart its objective of promoting competition from generic drug manufacturers. Concerns that drug manufacturers were able to "game the system"[2] ultimately led Congress to include in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, new provisions that underscored the pro-competitive purposes of the Hatch-Waxman Act.

The concerns that led to the 2003 amendments largely involved two devices employed under the Hatch-Waxman Act to slow generic competition against drugs subject to patent. The first was abuse of the 30-month stay of FDA approval once patent infringement litigation was filed: Pharmaceutical companies, Congress learned, had been able to obtain multiple, successive 30-month stays by invoking multiple patents allegedly protecting the same drug, resulting in "basically interminable stays." 149 Cong. Rec. S8193 (June 19, 2003) (statement of Sen. Gregg).

The second device that provoked Congress's disapproval (and that has now prompted the filing of the FTC's petition for certiorari in this case) was the use of settlement agree-

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[2] 149 Cong. Rec. S8190 (June 19, 2003) (statement of Sen. McCain) (quoting testimony of former FTC Chairman Timothy Muris); *see also id.* at S8193 (statement of Sen. Gregg) ("What we saw, regrettably, under Hatch-Waxman, was there were games being played.").

ments in patent litigation, where a manufacturer of a brand-name drug paid a generic manufacturer that had filed an ANDA to withhold the generic drug from the market even after the expiration of the 30-month stay on FDA approval. A 2002 Senate Report explained the problem as follows:

> The pharmaceutical industry has been able to reap significant profits by selling vitally important drugs to all consumers, especially senior citizens. However, the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives. ....
>
> Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug. The Federal Trade Commission reports that some firms are exploiting that provision of law by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.

S. Rep. No. 107-167, at 4 (June 20, 2002).[3]

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[3] Senate Report No. 107-167 concerned legislation passed by the Senate but not the House during the 107th Congress, which contained

(*Footnote continued*)

The Senate Report went on to explain how the economics of the prescription drug market created incentives for such anti-competitive agreements:

> Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the [patent-holder] and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the [patent-holder] following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.
>
> Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the [first ANDA] and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

Id. at 10.

The same concerns about anti-competitive agreements between name-brand and generic manufacturers that were set

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provisions that were ultimately included in the Hatch-Waxman Act amendments passed by the 108th Congress as part of the 2003 Medicare drug benefit legislation. There is no separate report concerning the amendments as enacted in the 108th Congress, other than a very brief discussion in the Conference Report focusing on other issues. H. Conf. Rep. 108-391, at 835-36 (Nov. 21, 2003).

forth in the 2002 Senate Report were repeated in the 2003 floor debates surrounding the Medicare drug legislation. Senator Gregg, one of the principal sponsors of the amendments to the Hatch-Waxman Act, explained that the "games" that gave rise to the amendments included "games on the generic side where they might team up with a brand name and take advantage of the 180-day exclusivity clause and never bring the drug to market even though they had filed." 149 Cong. Rec. S8193 (June 19, 2003). Senator Collins elaborated on the problem of anti-competitive settlement agreements between name-brand and generic manufacturers:

> One case involved the producer of a heart medication which brought a lawsuit for patent and trademark infringement against the generic manufacturer in early 1996. Instead of asking the generic company to pay damages, however, the brand name manufacturer offered a settlement to pay the generic company more than $80 million in return for keeping the generic drug off the market. In the meantime, the consumers of this heart medication, which treats high blood pressure, chest pains, and heart disease, were paying about $73 a month, while the generic would have cost them only $32 a month.

Id. at S8194.

The 2003 amendments sought to further the Hatch-Waxman Act's original goals of speeding the introduction of generic drugs to the market in a number of ways. First, they altered the 30-month stay provisions to address the problem of generics being blocked by multiple, successive stays. *See* Pub. L. No. 108-173 § 1101, 117 Stat. 2448 (amending 21 U.S.C. § 355(j)). Second, they added provisions to enhance the ability of a generic manufacturer that had filed an ANDA to bring a declaratory judgment action with respect to the validity or infringement of a patent covering the brand-name drug even if the brand-name manufacturer did not itself bring an infringement action, thus expediting the elimination of

uncertainty that might otherwise inhibit marketing of the generic version. *See id.* § 1101(a)(2)(C), 117 Stat. 2450 (adding 21 U.S.C. § 355(j)(5)(C)). Third, and most importantly here, the amendments required that all agreements between brand-name and generic manufacturers concerning the marketing of drugs subject to an ANDA be submitted to the FTC and the Justice Department for review, and provided that the generic manufacturer would forfeit its 180-day exclusivity rights if, as a result of enforcement action by either the FTC or the Justice Department, such an agreement were found to violate the antitrust laws or the FTC Act. *Id.* §§ 1102, 1111-18, 117 Stat. 2458-59, 2461-64 (codified at 21 U.S.C. § 355(j)(5)(D) and 21 U.S.C. § 355 note).

By subjecting agreements of the type at issue in this case to stringent governmental scrutiny and providing an additional penalty if they were found to violate the antitrust laws, the 2003 amendments underscored that the Hatch-Waxman Act was never intended to foster such anti-competitive arrangements. Indeed, all of the 2003 amendments were designed to counter anti-competitive practices that had arisen in the years following the Act's passage and to re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers.

III. The Eleventh Circuit's Decision Undermines the Hatch-Waxman Act's Pro-Competitive Policy.

The Eleventh Circuit turned the pro-competitive policy embodied in the Hatch-Waxman Act and the 2003 amendments on its head by asserting that the provisions of the Act somehow provided a *justification* for agreements under which generic manufacturers withheld their products from the market in return for payments from brand-name drug makers. Quoting *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003), the Eleventh Circuit criticized the FTC for "neglect[ing] to understand" that "reverse payments are a natural by-product of

the Hatch Waxman Act process." 402 F.3d at 1074. The Eleventh Circuit seemed to believe that because the Act created a situation where generic drug manufacturers *could* extract settlement payments in return for keeping their products off the market, such agreements were somehow competitively justified and, indeed, endorsed by the Act.

To be sure, the Hatch-Waxman Act enhanced the bargaining position of generic manufacturers in settlement negotiations by removing regulatory barriers to their entry into the market. But the reason the Act enhanced the position of the generics was to encourage them to enter the market, *not* to authorize them to use their increased leverage to exact a share of a name-brand drug owners' monopoly profits in return for *staying out of the market*. The Eleventh Circuit confused an unintended consequence of the original legislation—its creation of incentives for anti-competitive as well as competitive behavior—with its "natural" and intended effects.

Unlike the Eleventh Circuit, other courts have recognized that opportunities for anti-competitive agreements were by no means *natural* outgrowths of the Hatch-Waxman Act's purposes, but distortions of its intended effect. Even the *Ciprofloxacin* decision relied on by the Eleventh Circuit recognized that use of the Hatch-Waxman process to delay a would-be generic competitor's entry into the market through reverse payments is an "*unintended* consequence of altering the litigation risks of patent lawsuits." *Ciprofloxacin*, 261 F. Supp. 2d at 252 (emphasis added). Similarly, the D.C. Circuit has recognized that the statutory scheme creates an "unfortunate" opportunity for the "first applicant [to] collude[] with the pioneer drug company to eliminate generic competition." *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1067, 1072 (D.C. Cir. 1998). That result, however, is "at odds with Congress's apparent purposes, in enacting [the Hatch-Waxman Act], of rewarding innovation and bringing generic drugs to market quickly. Indeed, the first applicant

could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely." *Id.* at 1072; *see also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 768 (D.N.J. 1999) (stating that "taking advantage of the exclusivity period in an anticompetitive manner" would "fal[l] squarely within what the court in *Mova* speculated would be an abuse of the statute"); *In re Cardizem CD Antitrust Litigation*, 218 F.R.D. 508, 534 (E.D. Mich. 2003) (recognizing that Congress has "worked to amend Hatch-Waxman's exclusivity provisions to curb the very abuses alleged in this action"), *aff'd in part and app. dism'd in part*, 391 F.3d 812 (6th Cir. 2004), *cert. denied sub nom. Sams v. Hoechst Aktiengesellschaft*, 125 S. Ct. 2297 (2005).

Of course, whenever a statute is designed to foster competition, it may be "natural" for industry participants to respond by agreeing *not* to compete in order to share higher monopoly profits—"natural" in the sense that industry often tends toward anti-competitive behavior. But that tendency, whether "natural" or not, does not provide a competitive justification for such agreements when they are challenged under the antitrust laws—which, after all, are designed principally to curb such tendencies—nor does it demonstrate that the anti-competitive behavior is consistent with the aims of the underlying statute. Rather, as the Fifth Circuit has noted in a different context, "actions taken to 'subvert' [a regulatory] scheme 'for anticompetitive purposes' are subject to the antitrust laws." *Woods Exploration & Producing Co. v. Aluminum Co. of America*, 438 F.2d 1286, 1303 (5th Cir.1971).

More generally, the Eleventh Circuit's decision is in tension with decisions that have recognized, outside the settlement context, that use of the Hatch-Waxman process to prevent generic competition is impermissible because it would "turn the intent of the Hatch-Waxman Act on its head" and "allow, in effect, a monopoly . . . when such rights could not be obtained through the normal patent process." *Alcon Labo-*

ratories, Inc. v. Allergan, Inc., 256 F. Supp. 2d 1080, 1089 (C.D. Cal. 2003) (criticizing brand-name manufacturer's attempt to "effectively circumvent the rationale and intent of the Hatch-Waxman Act" by bringing an action for inducing infringement against a competing generic manufacturer prior to FDA approval); *see also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003) (noting need to ensure that "the incentive structure created by the Hatch-Waxman Amendments" not "be turned on its head"), *aff'd sub nom. Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). These courts have refused to permit drug manufacturers to use the Act as a "sword" to fend off competing generic manufacturers because "[t]hat would certainly not advance the purpose of making available 'more low cost generic drugs,' and was not what Congress intended." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003).

Moreover, the Eleventh Circuit's decision significantly undermines the effect of the 2003 amendments to the Hatch-Waxman Act. The amendments were designed to enhance the federal government's authority to police anti-competitive agreements between generic and brand-name drug manufacturers and to create a significant new disincentive to such agreements: forfeiture of the 180-day exclusivity period granted to the first generic manufacturer to challenge a patent if the generic is found to have entered an agreement with a brand-name manufacturer that violates the antitrust laws. However, in enacting the provisions for FTC and DOJ review of agreements between generic and brand-name manufacturers, as well as the new forfeiture provision, Congress relied on the adequacy of *existing* principles of antitrust law to condemn agreements whereby generics withheld drugs from the market in exchange for a share of the brand-name manufacturer's monopoly profits. *See* S. Rep. No. 107-167, at 1.

The Eleventh Circuit's aggressive second-guessing of the FTC's decision about the agreements in this case, and its er-

roneous notion that settlement agreements involving payments to generics to keep their products off the market are a natural consequence of Hatch-Waxman, threatens to render the mechanism Congress created to police anti-competitive agreements toothless. Because it seems to be based on the notion that Hatch-Waxman somehow dictates application of weaker-than-normal antitrust constraints to anti-competitive agreements such as those at issue here, the Eleventh Circuit's reasoning makes it doubtful whether any FTC enforcement action in this field can survive (particularly given that drug manufacturers will generally be free to mount any challenges to FTC activity in that court). The decision below thus stands as a significant obstacle to the accomplishment of Congress's intent, in the 2003 legislation, to correct the abuses that had arisen under the Hatch-Waxman Act and shore up the Act's principal purpose of increasing competition in the prescription drug market for the benefit of consumers.

The Eleventh Circuit concluded its opinion by stating that the result it reached "reflects policy." 402 F.3d at 1076. But *whose* policy? The policy the Eleventh Circuit chose to follow was one of its own invention, not the one chosen by Congress when it enacted the Hatch-Waxman Act and its 2003 amendments. Congress's clearly stated goal was to lower drug prices by enhancing generic drug competition. The predictable result of the policy the Eleventh Circuit has chosen to substitute for that of Congress will be less competition and higher drug prices for all Americans.

CONCLUSION

For the foregoing reasons, the FTC's petition for a writ of certiorari should be granted.

Respectfully submitted,

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